

**2016**

**Commissioning guide:**

## Gallstone disease

Sponsoring Organisation: Association of Upper gastrointestinal Surgeons

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## Glossary

<b>Term</b>	<b>Definition</b>
<b>AP</b>	Acute pancreatitis
<b>APA</b>	American Pancreatic Association
<b>CBD</b>	Common bile duct
<b>ERCP</b>	Endoscopic retrograde cholangiopancreatography
<b>IAP</b>	International Association of Pancreatology
<b>LBDE</b>	Laparoscopic bile duct exploration
<b>LC</b>	Laparoscopic cholecystectomy
<b>LFT</b>	Liver function test
<b>MRCP</b>	Magnetic retrograde cholangio pancreatogram
<b>NOTES</b>	Natural orifice transluminal endoscopic surgery
<b>RUQ</b>	Right upper quadrant
<b>SILS</b>	Single incision laparoscope surgery
<b>SWORD</b>	Surgical workload outcomes research database
<b>UGI</b>	Upper gastrointestinal

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## Introduction

This guidance focuses on the treatment of patients aged 18 years and over with gallstones. In the UK around 10–15% of the adult population have gallstones.

The majority of people with gallbladder stones remain asymptomatic and require no treatment. Presentation is usually with upper abdominal/right upper abdominal pain exacerbated by eating or with a complication such as inflammation of the gallbladder (Cholecystitis). The definitive treatment of symptomatic gallbladder stones is surgical removal of the gallbladder.

Stones may pass from the gallbladder into the common bile duct.

Common bile duct (CBD) stones may present with symptoms of jaundice, cholangitis or pancreatitis, or be asymptomatic. All CBD stones should be referred for consideration of treatment because of the risk of potential severe complications

Around 60,000 cholecystectomies were performed in England in Q1 to Q4 2014/15 with over a threefold variation across clinical commissioning group (CCG) areas, ranging from 48 procedures per 100,000 population to 177 procedures per 100,000 population (Fig 1). This variation may be due to a variety of reasons including lower thresholds to perform surgery in some CCGs or under referral in others.

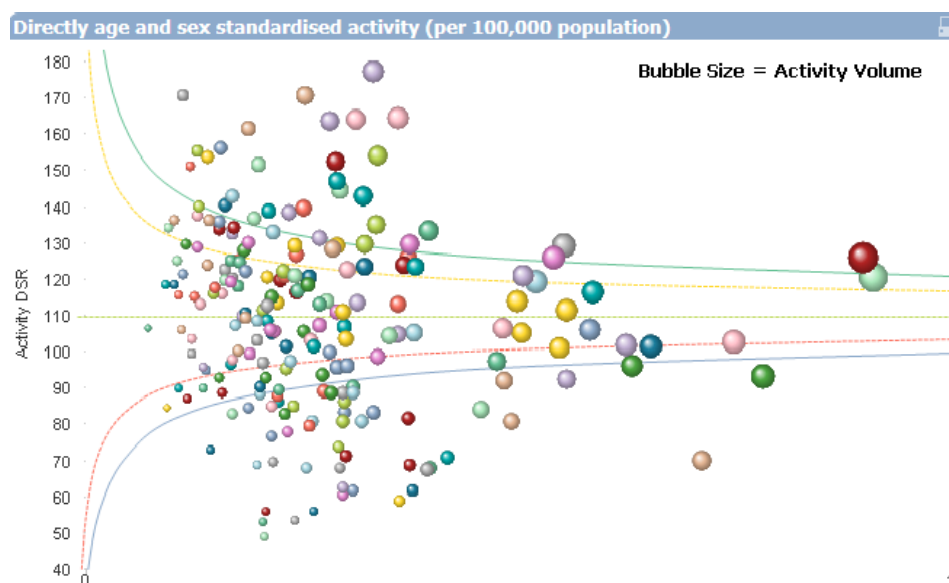


Figure 1: Age and sex standardised activity volume of cholecystectomies per 100,000 population per CCG (each bubble representing a CCG) for Q1 to Q4 2014/15

The above information is available in an [interactive web-based tool](#) allowing CCGs to drill down into their own data.

## 1. High Value Care Pathway for Gallstones

### 1.1 Primary care

#### *Referral*

- Patients with an incidental finding of stones in an otherwise normal gallbladder require no further investigation or referral

#### *Primary care management*

- Most patients with symptomatic gallstones present with a self-limiting attack of pain that lasts for hours only. This can often be controlled successfully in primary care with appropriate analgesia, avoiding the requirement for emergency admission. When pain cannot be managed or if the patient is otherwise unwell (e.g. sepsis), he or she should be referred to hospital as an emergency
- Further episodes of biliary pain can be prevented in around 30% of patients by adopting a low fat diet. Fat in the stomach releases cholecystokinin, which precipitates gallbladder contraction and might result in biliary pain
- Patients with suspicion of acute cholecystitis, cholangitis or acute pancreatitis should be referred to hospital as an emergency
- There is no evidence to support the use of hyoscine or proton pump inhibitors in the management of gallbladder symptoms
- Antibiotics should be reserved for patients with signs of sepsis
- There is no evidence of benefit from the use of non-surgical treatments in the definitive management of gallbladder stones (e.g. gallstone dissolution therapies, ursodeoxycholic acid or extracorporeal lithotripsy)<sup>6</sup>

#### *Best practice referral guidelines*

- Epigastric or right upper quadrant pain, frequently radiating to the back, lasting for several minutes to hours (often occurring at night) suggests symptomatic gallstones. These patients should have liver function tests checked and be referred for ultrasonography

- Confirmation of symptomatic gallstones should result in a discussion of the merits of a referral to a surgical service regularly performing cholecystectomies. Laparoscopic Cholecystectomy (LC) can be performed with a very low serious complication rate and is recommended that surgeons should be performing a minimum of at least 10 procedures a year to maintain their skills<sup>4</sup>
- Following treatment for CBD stones with endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy, removal of the gallbladder should be considered in all patients. However, in patients with significant co-morbidities, the risks of surgery may outweigh the benefits
- Patients with known gallstones with a history of acute pancreatitis should be referred for a cholecystectomy to a surgical service and surgeons regularly performing the procedure
- Patients with known gallstones and jaundice or clinical suspicion of biliary obstruction (e.g. significantly abnormal liver function tests) should be referred urgently to a gastroenterology or surgical service with expertise in managing biliary diseases

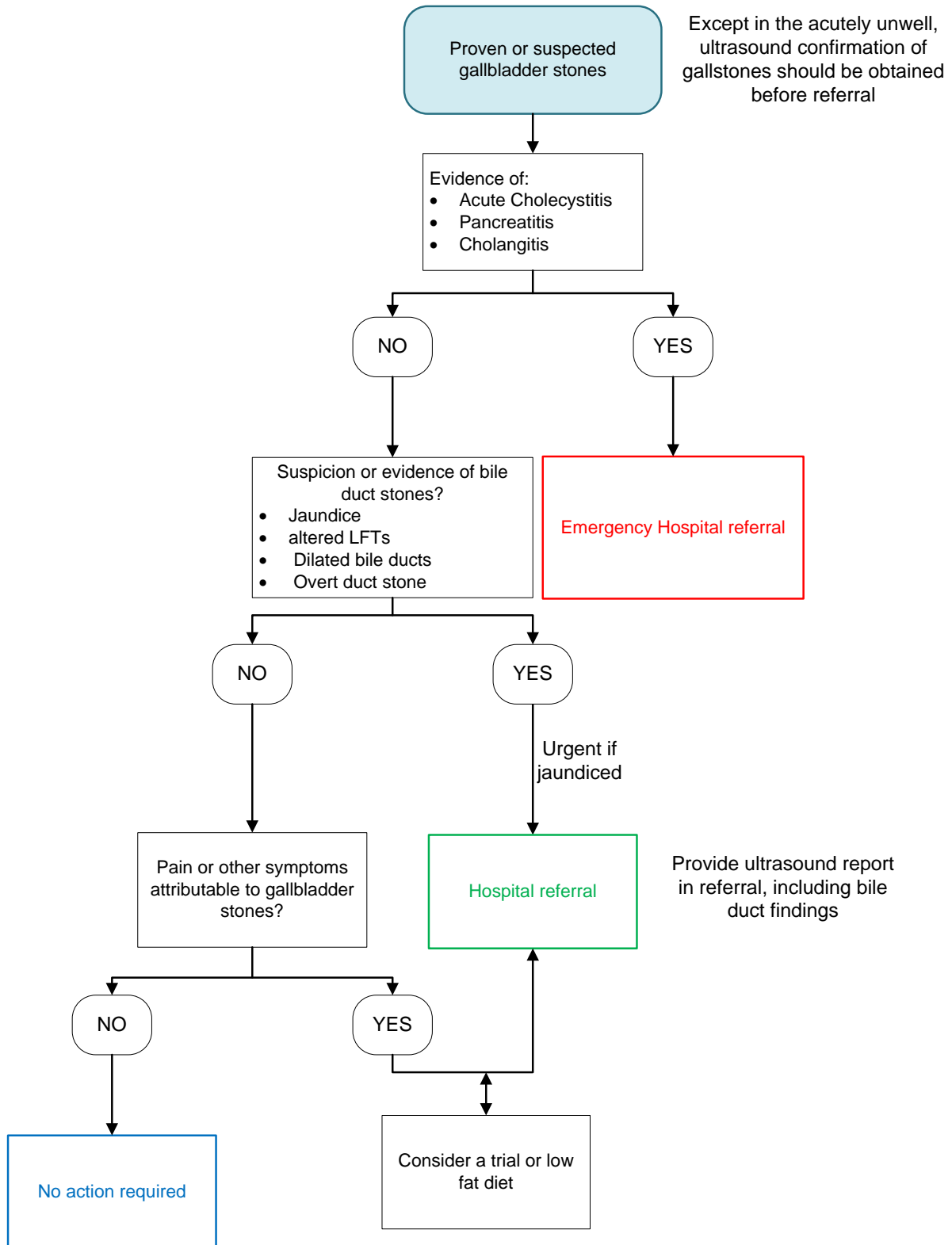
#### 1.2 Secondary Care

- In patients with symptomatic gallstones, the decision to operate is made by the patient with guidance from the surgeon. This will include assessment of the risk of recurrent symptoms and complications of the gallstones (50% risk per annum of further episode of biliary colic and 1–2% risk per annum of development of serious complications), and the risks and complication rates of surgery in relation to the individual patient's co-morbidities and preference<sup>7</sup>
- Patients with mild acute gallstone pancreatitis should undergo definitive treatment (usually cholecystectomy although an endoscopic sphincterotomy may be appropriate in frail patients) ideally on the same admission or if discharged home, within 2 weeks of presentation (e.g. this guidance excludes patients with severe pancreatitis who represent c.10% of all pts with AGP)<sup>5</sup>
- Patients with Acute Cholecystitis should ideally have LC during the same admission or within 7 days<sup>1</sup>
- Patients with abnormal liver function tests (with or without dilated bile ducts) on ultrasound but without frank jaundice or cholangitis, have <15% risk of CBD stones and may proceed to LC without additional pre-operative imaging. Per-operative on-

table cholangiography followed by laparoscopic bile duct exploration or post-operative ERCP is a more cost effective and safe approach<sup>3</sup>. If pre-operative imaging is required magnetic resonance cholangiopancreatography or endoscopic ultrasonography should replace ERCP which should be reserved for therapy, not as a diagnostic test

- Patients with symptomatic CBD stones should undergo CBD stone extraction by ERCP or surgical bile duct exploration (laparoscopic or open). A single stage LC & LBDE offers improved resource utilisation, reduced costs and lower length of stay compared to a two-stage ERCP and LC strategy<sup>4</sup>. Patients with asymptomatic gallstones in the bile ducts should also be considered for stone extraction<sup>8</sup>
- The laparoscopic approach to cholecystectomy should be considered the standard procedure for the majority (>98%) of patients. Exceptions are rare but include multiple previous laparotomies and RUQ stomas. The majority of elective patients are suitable for daycase surgery<sup>2</sup>
- Secondary providers offering cholecystectomy must be able to offer intraoperative on-table cholangiography and have arrangements in place for urgent access to ERCP and interventional radiology for the management of postoperative complications
- Patients who have significant symptomatic gallstone disease sufficient to require intra-pregnancy surgery are best managed with a LC during the second trimester when organogenesis is complete.<sup>9</sup> Patients with mild gallstone related symptoms should undergo LC after delivery
- Patients who have a suspected bile duct injury should be referred to their regional tertiary hepatopancreatobiliary service
- At present there is no evidence to show any benefits of SILS or NOTES other than the reduction in the number of incisions used. A case for robotic surgery in cholecystectomy has not been demonstrated

Care pathway for gallstone disease





## 2. Procedures explorer for Gallstone disease

Users can access further procedure information based on the Hospital Episode Statistics data available in the quality dashboard to see how individual providers are performing against the indicators. This will enable CCGs to start a conversation with providers who appear to be ‘outliers’ from the indicators of quality that have been selected.

The procedures explorer tool is available via the [Royal College of Surgeons](#) website.

Within the tool there is also a [Meta data document](#) to show how each indicator was derived.

Full [instructions](#) are also available, which explain how to interpret the data.

## 3. Quality dashboard for Gallstone disease

The quality dashboard provides an overview of activity commissioned by CCGs from the relevant pathways and indicators of the quality of care provided by surgical units.

The quality dashboard is available via the [Royal College of Surgeons](#) website.

Example quality dashboard for Q1 to Q4 2014–2015

### NHS NOTTINGHAM CITY CCG

### General Surgery-Gall Bladder Disease

#### Gallstones

Metric	Period	Value	Mean	Chart	Trend
Percentage of laparoscopic cholecystomies	RY Q1 1415	95.85	95.51		
Proportion of patients with an emergency admission for gallstones disease who have a cholecystectomy within 10 days of admission	RY Q1 1415	23.97	14.80		
Proportion of day case cholecystomies that are converted to In Patient	RY Q1 1415	6.37	36.12		
Proportion of patients with ERCP who have had another Gallstones related ERCP within 1yr	RY Q1 1415	0.00	8.58		
Proportion of emergency admissions for gallstones disease within 1yr of a previous admission for gallstone disease	RY Q1 1415	15.68	16.26		

#### *Bespoke Measures*

The following information is currently being developed for inclusion in the quality dashboards:

1. Proportion of patients with an emergency admission for gallstone disease (excluding pancreatitis) who have a cholecystectomy within ten days of initial admission date
2. Proportion of patients with an emergency admission for gallstone associated pancreatitis who have a cholecystectomy within 14 days of discharge from the initial admission
3. Proportion of elective cholecystectomies completed laparoscopically
4. Proportion of day-case cholecystectomy patients who are converted to inpatients
5. Rate of unscheduled readmission for gallstone disease within one year of any previous gallstone disease admission
6. Proportion of patients who have ERCP who have previously undergone one or more ERCP procedures for gallstone disease, within one year (attributed to site that performed the first ERCP)
7. Rate of bile duct injuries (defined as patients who go on to have major reconstruction, excluding patients with cancer)

## 4. Levers for implementation

### *4.1 Audit and peer review measures*

The following measures and standards are those expected at primary and secondary care. Evidence should be able to be made available to commissioners if requested.

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	<b>Measure</b>	<b>Standard</b>
<i>Audit</i>	Provider can demonstrate regular local audit for cholecystectomy and ERCP outcomes, in reference to any national	

	guidelines	
<i>Patient care pathway</i>	Providers can demonstrate implementation of developed patient care pathway across primary, secondary and tertiary care	
<i>Laparoscopic cholecystectomy (LC) for acute gallstone pancreatitis</i>	Should conform with IAP/APA international guidelines of LC on same admission for patients with mild AP (without other contraindications)	Quality dashboard

#### 4.2 Quality Specification/CQUIN

<b>Measure</b>	<b>Description</b>	<b>Data specification (if required)</b>
Readmission rates after cholecystectomy within 30 days	Readmission rates should be <10%	Procedure explorer
Day-case rates	Provider demonstrates day-case rates for LC	Procedure explorer
Proportion of admitted patients undergoing emergency cholecystectomy	High volume of patients treated by cholecystectomy within index admission (>25%)	Quality dashboard (Bespoke Measure 1)
Proportion of patients undergoing elective laparoscopic surgery	Low rates of planned open cholecystectomy	Quality dashboard (Bespoke Measure 3)
Day -case LC admission rates	Low rates of admission after day-case LC (<5%)	Quality dashboard
Timely management of gallstone disease	Patients with symptomatic gallstone disease sufficient to cause acute admission should have timely definitive management	Quality dashboard (Bespoke Measure 6)

Safety of LC	Zero bile duct injury rates	Quality dashboard (Bespoke Measure 7)
Minimum cholecystectomy caseload	Individual surgeons should be performing at least 10 LC PA	SWORD

## 5. Directory

### 5.1 Patient Information for Gallstone disease

Name	Publisher	Link
<i>Gallstones</i>	British Society of Gastroenterology	<a href="http://www.bsg.org.uk/patients/general/gallstones.html">http://www.bsg.org.uk/patients/general/gallstones.html</a>
<i>Gallstones</i>	British Liver Trust	<a href="http://www.britishlivertrust.org.uk/liver-information/liver-conditions/gallstones/">http://www.britishlivertrust.org.uk/liver-information/liver-conditions/gallstones/</a>
<i>Gallstones</i>	NHS Choices	<a href="http://www.nhs.uk/conditions/gallstones/">http://www.nhs.uk/conditions/gallstones/</a>
<i>Gallstones</i>	Patient.co.uk	<a href="http://patient.info/health/gallstones-leaflet">http://patient.info/health/gallstones-leaflet</a>
<i>Gallstones patient decision aid</i>	NHS England	<a href="http://sdm.rightcare.nhs.uk/pda/gallstones/">http://sdm.rightcare.nhs.uk/pda/gallstones/</a>

### 5.2 Clinician information for Gallstone disease

Name	Publisher	Link
<i>Gallstones</i>	NICE	<a href="http://www.evidence.nhs.uk/topic/gallstones">http://www.evidence.nhs.uk/topic/gallstones</a>
<i>Evidence-based guidelines for the management of acute pancreatitis</i>	IAP/APA	<a href="http://www.pancreatology.net/article/S1424-3903(13)00525-5/pdf">http://www.pancreatology.net/article/S1424-3903(13)00525-5/pdf</a>
<i>Quality and Safety Indicators of Endoscopy</i>	Joint Advisory Group on GI Endoscopy	<a href="http://www.bsg.org.uk/pdf_word_docs/bsg_grs_indic.pdf">http://www.bsg.org.uk/pdf_word_docs/bsg_grs_indic.pdf</a>
<i>Pathway for the management of acute gallstone disease</i>	AUGIS	<a href="http://www.augis.org/wp-content/uploads/2014/05/Acute-Gallstones-Pathway-Final-Sept-2015.pdf">http://www.augis.org/wp-content/uploads/2014/05/Acute-Gallstones-Pathway-Final-Sept-2015.pdf</a>
<i>Guidelines on the management of common bile</i>	BSG	<a href="http://www.bsg.org.uk/attachments/127_cbd">http://www.bsg.org.uk/attachments/127_cbd</a>

<i>duct stones (CBDS)</i>		<a href="#">s_08.pdf</a>
<i>The Provision of Services for Upper Gastrointestinal Surgery</i>	AUGIS	<a href="http://www.augis.org/wp-content/uploads/2016/06/Provision-of-Services-June-2016.pdf">http://www.augis.org/wp-content/uploads/2016/06/Provision-of-Services-June-2016.pdf</a>
<i>Endoluminal gastroplication for gastro-oesophageal reflux disease (IPG404)</i>	NICE	<a href="https://www.nice.org.uk/guidance/ipg404">https://www.nice.org.uk/guidance/ipg404</a>

## 6. Benefits and risks of implementing this guide

Consideration	Benefit	Risk
<i>Patient outcome</i>	Ensure universal access to best quality, timely and effective surgical treatment	
<i>Patient safety</i>	Reduce injury and readmission rates arising from gallstone disease	Complications of surgery or ERCP
<i>Patient experience</i>	Improve access to patient information sites	Poor dissemination or uptake of pathway
<i>Equity of access</i>	Equalise access rates nationally	Increase in marginal decisions in favour of surgery
<i>Resource impact</i>	Reduce unnecessary referral to non-surgical units where intervention not available	Increase in demand for services and pressure on non-gallstone disease related services elsewhere

## 7. Further information

### 7.1 Research recommendations

- Patient reported outcome measures – treated versus untreated mildly symptomatic gallbladder stones

- C-Gall study (Jane Blazeby / Irfan Ahmed )
- Management of patients with symptomatic gallstone and abnormal LFTs
- Optimal management of large CBD stones
- Management of asymptomatic CBD stones

#### 7.2 Other recommendations

- Development of a national registry for bile duct injuries

#### 7.3 Evidence base

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#### 7.3Bibliography

- NICE Guidance: Gallstone disease diagnosis and initial management (CG188) - Published October 2014

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- AUGIS Guidance: Emergency General Surgery Report – Published September 2015
- AUGIS Guidance: Pathway for the Management of Acute Gallstone Diseases – Published 2015
- AUGIS Guidance: The Provision of Services for Upper Gastrointestinal Surgery - Published April 2016

#### *7.4 Guide development group for Gallstones*

A commissioning guide development group was established to review and advise on the content of the commissioning guide. This group met once, with additional interaction taking place via email and teleconference.

<b>Name</b>	<b>Job Title/Role</b>	<b>Affiliation</b>
Ian Beckingham	Chair, Consultant General Surgeon	Association of Upper Gastrointestinal Surgeons (AUGIS)
Stephen Fenwick	Consultant General Surgeon	Great Britain and Ireland Hepato Pancreato Biliary Association (GBIHPBA)
Nick Everitt	Consultant General Surgeon	AUGIS
Mark Deakin	Consultant General Surgeon	AUGIS
Christian Macutkiewicz	Consultant General Surgeon	GBIHPBA
John Painter	Consultant Gastroenterologist	British Society of Gastroenterology (BSG)
Ruth Marsden	Vice-Chair	Healthwatch and Public Involvement Association
Richard Day	Secondary Care Doctor	Southampton City CCG

#### *7.4 Funding statement*

The development of this commissioning guidance has been funded by the following sources:

- The Royal College of Surgeons of England funded the costs of literature search

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- The Association of Upper Gastrointestinal Surgeons (AUGIS) of Great Britain and Ireland supported the meetings and administration to support the guideline development

#### 7.5 *Conflict of interest statement*

Individuals involved in the development and formal peer review of commissioning guides are asked to complete a conflict of interest declaration. It is noted that declaring a conflict of interest does not imply that the individual has been influenced by his or her secondary interest. It is intended to make interests (financial or otherwise) more transparent and to allow others to have knowledge of the interest.

The following interests were declared by members:

<b>Name</b>	<b>Job Title/Role</b>	<b>Interest</b>
George Webster	Gastroenterologist	<ul style="list-style-type: none"><li>• Fees for consultancy</li><li>• Fees for speaking at meeting/symposium</li><li>• Sponsorship for attending a meeting</li></ul>
Christian Macuketiewz	Consultant General Surgeon	<ul style="list-style-type: none"><li>• Fees for speaking at symposium</li></ul>

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